UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES ONLY TO: **THE WAVE 1 CASES IDENTIFIED IN EXHBIT A TO ETHICON'S MOTION**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE TO DEFENDANT'S MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY DR. DUNN PH.D.

Ethicon's Motion to Exclude the Opinions and Testimony of Dr. Russell Dunn, Ph.D., ("the Motion" or "Ethicon's Motion"), is fundamentally flawed in that it manipulates testimony to make it appear as though Dr. Dunn is not qualified, or that he otherwise does not have the requisite knowledge, to offer the product design and risk assessment opinions put forth in his report. On the contrary, Dr. Dunn is more than qualified to offer the opinions set forth in his Wave 1 report. Moreover, he relies upon not only his own vast experience, but also thousands of pages of Ethicon's internal documents, over 25 depositions (and exhibits thereto) of Ethicon employees involved in the design and launch of all of Ethicon's mesh products at issue, every internal polymer failure analysis study ever performed on anything made of Prolene (that has been produced), the design history files and technical files of all products involved in this litigation, and the ample, relevant peer-reviewed literature on polymer failure analysis and the principles of device design and risk analysis.[1]

[1] Ex. A, Dunn Report; *see also* Ex. D, Dunn Reliance List.

Ethicon's Motion expends a great deal of effort trying to make it appear as though Dr. Dunn did not review or rely on these materials to form his opinions—but this is simply not the case. Ethicon does not raise a single legitimate criticism of Dr. Dunn's opinions in these cases; instead, the arguments are based on a faulty understanding of medical device manufacturers' risk management systems and risk analyses. The Motion also spends most of its length cherry-picking out-of-context testimony and then twisting those statements to make it appear as though Dr. Dunn is unqualified and that his opinions are unsupported. At its core, Ethicon's arguments show a lack of understanding of the principles of device design and risk management, and how the relevant standards from the International Organization for Standardization ("ISO") are applied.

Dr. Dunn's opinions are separated into two sections: (1) Polymer Failure Opinions; and (2) Product Design Opinions.[2] His Polymer Failure Opinions are unchallenged, and there is no basis to exclude those opinions. Moreover, Dr. Dunn's opinions and methodology have not changed since he was vetted to testify by this Court in the *Huskey* litigation.[3] He should be allowed to testify in this Wave as well.

This Court has allowed the kind of expert testimony that Ethicon seeks to exclude here on several occasions.[4] This Court has routinely held that experts with qualifications similar to Dr. Dunn's are permitted to offer general causation opinions based upon: (1) the peer-reviewed scientific literature, (2) their education and experience, and (3) their review of SEM images and

[2] *See* Ex. A, Dunn Report
[3] *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710-711 (S.D. W. Va. 2014).
[4] *See, e.g., Huskey*, 29 F. Supp. 3d 691; *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195 2013 U.S. Dist. LEXIS 149976, (S.D. W.V. Oct. 18, 2013); *Mathison* v. *Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 U.S. Dist. LEXIS 59047 (S.D. W. Va. May 6, 2015).

other relevant evidence—and there is no reason why the Court should reverse its previous rulings (and the other progeny of *Daubert*) in the present case.[5]

STANDARD OF LAW

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995).

The Court's focus in a *Daubert* inquiry should be solely on the expert's "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Notably, "the Supreme Court itself viewed *Daubert* as a *liberalization*, not a tightening, of the rules controlling admission of expert testimony." *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996) (emphasis added). Further, "exclusion is the least favored means of rendering questionable scientific evidence ineffective." *Id.*

ARGUMENT

I. DR. DUNN'S OPINIONS ARE RELEVANT AND RELIABLE

Ethicon's arguments to exclude the testimony of Dr. Dunn are not supported by any legal precedent, and are actually undermined by the prior ruling of this Court. Indeed, Dr. Dunn was vetted and allowed to testify in *Huskey*, where this Court held: "[an] expert's testimony must help the jury to 'understand the evidence or to determine a fact in issue.' Fed. R. Evid. 702. This testimony assists the jury in determining whether Ethicon was negligent in designing the TVT-O.

[5] *Id.*

Therefore, Ethicon's motion to exclude Dr. Dunn's risk assessment opinions is DENIED."[6] Dr. Dunn's opinions are similarly relevant to the ultimate question of liability that the jury will be asked to decide in these Wave cases; and they are reliably based in the scientific method and are otherwise sound under FRE 702 and *Daubert*.

1. Dr. Dunn is qualified to render his opinions.

a. Dr. Dunn is an expert in utilizing the FMEA, and his FMEA opinions are uncontested.

Ethicon repeatedly argues that Dr. Dunn is not qualified to offer opinions regarding its quality systems or its risk analyses for mesh products, but those arguments are fundamentally flawed.[7] Ethicon argues that Dr. Dunn must be an expert in biomaterials, medicine, pathology, and seemingly every other field that may have contributed to the design and quality systems for the meshes at issue.[8] But these arguments ignore the specific field of scientific inquiry where Dr. Dunn has expertise—and the field in which he offers opinions in these cases—product design. For example, Ethicon argues that Dr. Dunn would need to be an expert in biomaterials to opine on the mechanism by which Prolene oxidizes *inside the body*. But his expertise is in device design, and he is not testifying about how Prolene oxidizes inside the body—he is testifying that the Failure Modes and Effects Analysis ("FMEA") for the products in question are not being utilized correctly, and those opinions are not challenged. Dr. Dunn is unquestionably an expert in how devices are designed and how their safety is maintained with risk analyses as part of a larger risk management plan.

[6] *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710 (S.D. W. Va. 2014).
[7] *See* Def's Motion, generally.
[8] Def's Motion at 2-4, 6, 8, 13, 14, 16, 17, and 20.

b. ISO 14971 is an international standard covering risk management for medical device manufacturers—and risk analysis, such as Ethicon's FMEA risk analysis is only one part of the risk management process.

Dr. Dunn explains in his report that every product manufacturer needs a risk management plan in place for every product sold.[9] ISO 14971 is an international standard that covers risk *management* for medical devices. *In part*, ISO 14971 describes standards for how a risk *analysis* for a medical device should be performed—but a risk analysis is only one component of a larger risk management plan.[10] It is the Standard Operating Procedure ("SOP") at Ethicon to utilize the FMEA risk analysis to assess, investigate, and mitigate every potential risk before (and after) any medical device is launched.[11] Dr. Dunn does not offer an opinion on every aspect of Ethicon's risk management plan under ISO 14971, but instead he only offers his opinion on whether Ethicon followed its FMEA risk analysis. Dr. Dunn's opinion is that Ethicon is not following the requirements of the FMEA risk analysis for the devices at issue, and because the FMEA is not being performed correctly, the requirements of the larger risk management plan are also not being satisfied.[12]

None of these facts are disputed in Ethicon's Motion; however, Plaintiffs' believe this clarification is necessary, as Ethicon's arguments seem to confuse the broader issue of risk *management* with Dr. Dunn's more specific opinions regarding FMEA risk *analysis*.

[9] Ex. A, Dunn Report at 21.
[10] *Id.*
[11] *Id.* at 19.
[12] To be clear, ISO 14971 provides standards for how to create and maintain a risk management plan specific to medical devices—and ISO 14971 also requires that a risk analysis be put in place for every medical device as part of a risk management plan. Ex. A, Dunn Report at 21. The FMEA is a mode of risk analysis that encompasses all of the standards imposed by ISO 10993—including the need to test for degradation and oxidation. *Id.* Dr. Dunn is an expert at applying and utilizing FMEAs and does not need to be an expert in biomaterials, medicine, pathology, or complaint handling to hold his opinions. *Id.*

c. The FMEA is the only risk analysis used at Ethicon and Dr. Dunn is an uncontested expert in utilizing it.

Ethicon's Motion ignores the fact that the SOP at Ethicon is to use the FMEA for every medical device that it produces, and that there is no other mode of risk analysis that Ethicon will use for its risk management. There is only the FMEA. Instead, Ethicon argues that the risk analysis standards outlined in ISO 10993 are controlling:

> ISO 14971 "specifically direct[s] that the reader refer to ISO 10993 for guidance on the general principles for biological evaluation, or biocompatibility, of medical devices. This expressly includes risk analysis concerning the "chemical nature of the materials" and the "influence of biodegradation."[13]

Yet the Motion acknowledges that the FMEA is a recommended mode for medical device risk analysis by ISO 14971:

> ISO 14971 defines a "risk analysis" as a "[s]ystematic use of available information to identify hazards and to estimate risk." Nowhere in ISO 14971 is there any requirement that risk analysis be documented in any particular format. Note 2 under Section 4.1 of ISO 14971 references merely as examples "some risk analysis techniques are described in Annex G." An FMEA format is but one of the sample techniques listed in Annex G.[14]

Ethicon's Motion misses the point of what product design entails—and what actually happens internally at Ethicon—which is to require that the FMEA is used to assess the risks associated with in all of its products.[15]

d. Dr. Dunn opines that the FMEA was not utilized properly for the devices at issue.

Dr. Dunn has opined that the FMEA was not properly used to identify or mitigate potential risks associated with Prolene's oxidation and degradation of the pelvic mesh products at issue.[16] The FMEA *requires* that every potential failure mode be described, investigated and

[13] Def's Motion at 4, citations omitted.
[14] Def's Motion at 8, citation omitted.
[15] Ex. A, Dunn Report at 19.
[16] *Id.*

mitigated, both before a product is launched and while it is on the market.[17] Under the rules for utilizing the FMEA risk analysis for medical devices, every potential failure mode is to be recorded in the FMEA and investigated, it is a living document.[18]

As Dr. Dunn explained, it is of no consequence if the medical device manufacturer *believes* if the failure mode will lead to clinical complications or not; the potential failure mode *must* be described in the FMEA, and then investigated, no matter what.[19] Oxidation of Prolene, however, is not described as a potential failure in any of the FMEA documents associated with the products at issue.[20] This is true despite the fact that the available literature states that polypropylene blends can oxidize and lose their mechanical properties, and Ethicon even performed several internal oxidation studies that concluded Prolene oxidizes and degrades after implantation.[21] As such, oxidation *should* be described in the FMEA, but it is not.[22] Indeed, if the FMEA had identified oxidation as a potential failure mode, the FMEA process would require that an investigation take place into how or if mesh oxidation can injure women implanted with these products.[23] And since the FMEA risk analysis portion of the larger risk management plan is not functioning as it should, the risk management plan is broken for the same reason.[24]

2. Dr. Dunn's oxidation-related opinions are within his area of expertise.

Dr. Dunn's opinions on the inherent chemical nature of polypropylene to oxidize, and on how Ethicon's devices were not designed with this fact in mind, are central to the jury understanding the defective nature of the products at issue. The science is sufficiently settled on

[17] *Id*. at 21-23.
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.* at 28-31.
[22] *Id.*
[23] *Id.*
[24] *Id.*

this issue, and it is not even challenged in Ethicon's Motion. Polypropylene must be stabilized against oxidation in order for it to have any use at all, and the Polymer Failure opinions offered by Dr. Dunn, which include his reliance on all of the internal oxidation studies performed, are not being challenged *at all* in Ethicon's Motion.

Instead, Ethicon only takes issue with Dr. Dunn's opinions on Product Design and Risk Analysis. And to be clear, Dr. Dunn's opinions on Product Design and Risk Assessment are, in part, based on what he has seen internally with regard to Prolene's *in vivo* oxidation studies as well as the specific findings and design activities taken by the Ethicon employees who developed these products.[25]

3. Ethicon's Motion is intentionally confusing and cumbersome.

Ethicon's Motion is almost entirely based on misleading statements and inaccurate paraphrasing of testimony that only serve to confuse the issues present. Fundamentally, all of Ethicon's complaints are grounds for cross-examination, not exclusion. *See In re: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, No. 3:11-MD-2244-K 2014 U.S. Dist. LEXIS 97798, at *45 (N.D. Tex. July 18, 2014). But while Ethicon's contentions may be relevant for cross-examination, simply putting words into an expert's mouth is not a grounds for exclusion.

For example, Ethicon states: "Dr. Dunn admits that he is not qualified to opine whether Prolene does in fact undergo oxidative degradation in the body."[26] Dr. Dunn has never held himself out as being an expert about how the human body reacts with Prolene to oxidize it, but Dr. Dunn does make it clear in his report (and in the actual testimony cited by Ethicon) that he is an expert on polymer failure and analysis, as well as an expert on device design and risk

[25] Ex. A, Dunn Report at 19-30.
[26] Def's Motion at 3.

assessment.[27] As such, Dr. Dunn's opinions only focus on device design and polymer failure analysis. The Motion continues: "Dr. Dunn has no expertise relating to biocompatibility. In fact, he does not even know what a biocompatibility risk assessment is."[28] Again, Dr. Dunn has never held himself out as an expert in biocompatibility, specifically, and a biocompatibility risk assessment is only part of the larger framework of device design and risk assessment where Dr. Dunn has expertise. As he testified:

> Q. Have you considered any of Ethicon's biocompatibility risk assessments?
> A. Yes. I've looked at their biocompatibility testing. I've looked at a lot of their testing. I'm telling you they did not consider oxidative degradation in this risk analysis. And that's clearly evident by the listing of questions that I provided in my report.[29]

Ethicon's entire Motion is based on inconsistencies similar to what is described above. Plaintiffs will address each of the arguments below (in the order they are made in Ethicon's Motion), but Dr. Dunn's opinions are clearly stated in his report. And the documents, depositions, clinical literature and other support that he relied upon to form those opinions are also detailed therein. There is absolutely nothing in Ethicon's Motion that takes away the relevance and reliability of the opinions that Dr. Dunn has put forth for these Wave 1 cases.[30]

II. PLAINTIFFS' RESPONSE TO DEFENDANT'S ARGUMENTS

A. Dr. Dunn is qualified to render his opinions.

1. Dr. Dunn has the requisite knowledge to offer his opinions on device design and polymer failure analysis.

Ethicon misstates Dr. Dunn's opinions to fit the arguments made against him. He has not, and will not, provided an opinion as to how Ethicon's Prolene undergoes oxidation inside the body, but he is an expert in the same chemical analyses that Ethicon used internally to

[27] *Id.*
[28] *Id.*
[29] Ex. B, Dunn 03/2016 Deposition at 115:3-10.
[30] *See* Ex. A, Dunn Report, generally; *see also* Ex. D, Dunn Reliance List

conclude that Prolene degrades inside the body.[31] And while Ethicon is correct that it is Dr. Dunn's opinion that the use of Prolene in this application is the result of failures in the FMEA risk analysis and risk management plan,[32] Ethicon incorrectly states that Dr. Dunn does not have the requisite knowledge to assess the design and quality systems involved.[33]

As Dr. Dunn's report states: "[the SOP] at Ethicon is to employ a Failure Modes and Effects Analysis to assess and mitigate these potential risks before any product is launched and while it is on the market. This SOP was not followed properly with respect to the Prosima, Prolift and Prolift+M devices."[34] Ethicon does not question Dr. Dunn's expertise in dealing with FMEAs, nor does it deny that its SOP is to employ the FMEA as the mode of risk assessment for all of its products. The only question put forth is to his qualifications in regards to *performing the tests* required by the FMEA and, evidently, ISO 10993. But regardless of whether he is qualified to perform those tests, he still has expertise in both product design and in utilizing FMEAs.

2. The Ethicon FMEA risk analysis upon which Dr. Dunn opines comports with ISO 14971's requirements.

Ethicon argues that Dr. Dunn has never designed a medical device following ISO 14971 and ISO 10993, and that he did not follow these standards properly in making his assessment that oxidation and degradation were not considered in the development of the products at issue.[35] But as Dr. Dunn explained to defense counsel, everything in ISO 14971 and ISO 10993 regarding a consideration of biocompatibility and chemical degradation is addressed in the FMEA risk

[31] Def's Motion at 2; *see also* Ex. C, Dunn 11/2015 Deposition at 43:10-58:15; *see also* Ex. A, Dunn Report.
[32] *Id.*
[33] Def's Motion at 3-4.
[34] Ex. A, Dunn Report at 19.
[35] Def's Motion at 4-5.

analysis.[36] There is no need for Dr. Dunn to return to the ISO standards to form his opinions because those standards specifically state that the FMEA contains everything that a medical device risk analysis needs. As his report states:

> Ethicon uses the recommendations in ISO 14971 as guidance for its risk analysis for medical devices, including the use of the failure mode and effects analysis, but the use of the FMEA is also mandated by internal SOP to provide a "methodology for evaluating and analyzing risks resulting from potential failure modes, with the objective of eliminating or minimizing these risks to an acceptable level with the current state of technology."[37]

Moreover, Ethicon's argument that Dr. Dunn needs to be an expert in medical device design or biocompatibility to offer his opinions has no merit. ISO 14971 is an international standard that describes how to perform a risk analysis on a medical device—but there are many modes of risk analyses—and one way is to use the FMEA. If Ethicon had chosen *another* risk analysis besides the FMEA—one that was somehow specific to medical device design—then Ethicon's arguments may have had some merit. But Ethicon's internal SOP *mandates* that the FMEA is the risk analysis to be used for all of the devices it sells. This is exactly the area where Dr. Dunn has extensive experience and expertise, and his testimony should not be excluded.

3. Dr. Dunn is qualified to opine on the deficiencies in Ethicon's quality systems because they are due to failures in the FMEA.

Ethicon points out that Dr. Dunn opines that there are no defined or written standards when it comes to addressing quality systems for the design of medical devices.[38] Dr. Dunn is not only correct on this point, he explained why at his deposition; namely: because every medical device manufacturer is different, there is no way to control the SOP of every manufacturer, and instead only guidelines are provided.[39] Moreover, his opinion is supported by the Code of

[36] Ex. C, Dunn 11/2015 Deposition at 186:9-23.
[37] Ex. A, Dunn Report at 21.
[38] Def's Motion at 6.
[39] Ex. C, Dunn 11/2015 Deposition at 19:12-22:4.

Federal Regulations ("CFR") (cited to in Ethicon's Motion)[40]—which does not lay out any specific standards in regards to how a quality system should be implemented. Instead, the CFR only states what a quality system should entail, and nothing detailing the day-to-day operations of the quality system is described.[41]

As previously explained, however, Ethicon internally *mandates* that the FMEA risk analysis is used with all of the products that it sells. And the FMEA requires that Ethicon take all of the available information from the field about potential failure modes and then apply them back into to the FMEA, making it a living document.[42] For decades, the literature has reported oxidation and degradation for polypropylene materials—*and* Ethicon has confirmed that Prolene oxidizes and degrades *in vivo*—yet, to this day, the FMEA for the devices at issue have no mention of an oxidation failure mode.[43] Dr. Dunn's opinions on Ethicon's quality systems being deficient are clearly relevant and reliable, and they should not be excluded.

4. Dr. Dunn is an expert on the FMEA and on analyzing polymer failure modes, not biocompatibility.

Ethicon also repeatedly argues that Dr. Dunn needs to be a biomaterials expert to opine about device design, but that is not the case where he is not providing a biomaterials opinion. Dr. Dunn does not need to be an expert in biocompatibility to assess if Ethicon is properly utilizing the FMEA. As stated above (and in his report), it is Dr. Dunn's opinion that the information from the field regarding an oxidative failure mode was never taken into account in

[40] Def's Motion at 6.
[41] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=820&showFR=1&subpartNode=21:8.0.1.1.12.2 (last accessed 5/8/16).
[42] Ex. A, Dunn Report at 30-31.
[43] *Id.*

the FMEA for these products—and that if Ethicon ever had, they would have found another suitable material for this application.[44]

B. Dr. Dunn's opinions are reliable.

1. Dr. Dunn is qualified to offer his criticisms of the FMEA utilized for these products.

a. Ethicon SOP mandates the FMEA be used.

Ethicon's argument that Dr. Dunn misapplied ISO 14971 is wrong.[45] In fact, it is Ethicon who misconstrues ISO 14971 in its Motion. As explained above, and as discussed in Dr. Dunn's report, ISO 14971 is an international standard for how to create and maintain a risk management plan for medical devices. ISO 14971 is an international standard, not a kind of risk analysis or risk management plan. Ethicon has its own risk management plan in place—which seeks to comport with the international standard—and part of that plan is to utilize the FMEA as its mode of risk analysis for each of its products. These facts are never challenged in Ethicon's Motion.

b. **The FMEA was not properly utilized in the products at issue.**

Ethicon next asserts that because Dr. Dunn misapplies ISO 14971, he refuses to go beyond the FMEA, and he ignores the biocompatibility analyses performed on the products at issue.[46] Again, Ethicon's arguments on this point are either misdirection, or they are simply mistaken. ISO 14971 is a guideline for what any risk management plan must contain, including a medical device risk analysis. The FMEA is a risk analysis that comports with everything that ISO 14971 requires. And the FMEA is the risk analysis that Ethicon *mandates* be used in all of its products. Any argument that Dr. Dunn's opinions are invalid because he is following the

[44] Def's Motion at 8-9; *see also* Ex. A, Dunn Report.
[45] Def's Motion at 8-11.
[46] *Id*. at 12-14

FMEA, *which is Ethicon's chosen risk analysis that comports with ISO 14971*, is at odds with itself.

2. Dr. Dunn does not agree that additional oxidation testing of Prolene mesh should have been skipped because ISO 14971 and 10993 caution that unnecessary testing should be avoided.

Ethicon asserts that it did not need to test if or how Prolene's *in-vivo* oxidation would harm women implanted with vaginal mesh. In doing so, however, Ethicon is simply disagreeing with, and not undermining the scientific reliability of, Dr. Dunn's opinions. Dr. Dunn fully agrees with every recommendation stated in ISO 14971, but Ethicon's arguments fail to grasp the concept that the FMEA comports with every standard for a medical device risk analysis that is described in ISO 14971—which includes the need for any biocompatibility testing or analysis described in ISO 10993.[47]

What Dr. Dunn disagrees with is Ethicon's argument that the Prolene meshes used in these pelvic applications did not need further testing after Ethicon found oxidative degradation occurring on Prolene *in vivo*.[48] Ethicon argues that these ISO standards "caution that unnecessary testing should be avoided"—but Ethicon is perfectly willing to implant these pelvic mesh products without understanding the effect that oxidative degradation has inside the female pelvis.[49] All of Dr. Dunn's well-supported opinions are in direct opposition to that argument. And itis not the Court's role on a *Daubert* motion to determine which side is correct. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999).

[47] *See* Def's Motion, generally.
[48] Ex. A, Dunn Report at 19.
[49] Def's' Motion at 15.

3. Dr. Dunn is not a medical doctor, and he is not trying to associate clinical harm with Prolene's *in vivo* oxidation.

Ethicon's argument that Dr. Dunn is not qualified to testify regarding the clinical complications associated with the Prolene in Ethicon's mesh products seeks to confuse the issues in this case. Dr. Dunn does not provide any opinions on the clinical harm of the oxidative process, or the results of the degradation process *in vivo*.[50] Dr. Dunn will defer to other experts to speak to the clinical complications of Prolene oxidation and degradation inside the body.

4. Dr. Dunn is not a biomaterials expert.

Similarly, as explained above, Dr. Dunn has not and will not hold himself out as a biomaterials expert who is capable of testifying about how the body reacts with and oxidizes Prolene meshes.

5. ISO 14971 is a standard not a mode of risk analysis.

As explained above, ISO 14971 is an international standard that describes how to create and maintain a risk management plan for medical device manufacturers, including the requirement that every medical device have a risk analysis to maintain its safety, Ethicon mandates that the FMEA be used for its risk management plan to properly function. Dr. Dunn is an expert on device design, risk management, and risk analysis—those opinions are never questioned in Ethicon's Motion. Instead, Ethicon argues that Dr. Dunn should have assessed the risk/benefit analyses for these products to properly assess the health of its risk management plan.[51] And although Ethicon is correct that a risk/benefit analysis is part of a risk management plan, the point has nothing to do with the issues present. Dr. Dunn's opinions are focused on how the FMEA risk analyses were not properly utilized and because of that, the risk management plan is not properly functioning.

[50] *See* Ex. A, Dunn report, generally.
[51] Def's Motion at 19.

C. Dr. Dunn's opinions are not unfairly prejudicial.

As explained above, in *Huskey*, this Court held that an "expert's testimony must help the jury to 'understand the evidence or to determine a fact in issue.' Fed. R. Evid. 702. This testimony assists the jury in determining whether Ethicon was negligent in designing the TVT-O. Therefore, Ethicon's motion to exclude Dr. Dunn's risk assessment opinions is DENIED."[52]

In an attempt to counter-act this established probative value, Ethicon simply argues that Dr. Dunn is wrong about the occurrence of oxidative degradation, and that he has not studied how much time it takes to occur.[53] First, Ethicon's assertion that Dr. Dunn is wrong, and oxidative degradation simply does not occur, is not the type of question that the Court should answer on a Daubert motion. *Westberry*,, 178 F.3d at 261. Second, with regard to the timing of that oxidative degradation, that question is, at best, a subject of cross-examination—it does not require the exclusion of Dr. Dunn's opinions. *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972 2014 U.S. Dist. LEXIS 92316, 4 (S.D. W. Va. July 8, 2014); *see also Pugh*, 361 Fed. Appx. at 456 (Any weaknesses in the underpinnings of an expert's opinion go to the opinion's weight, rather than its admissibility). As such, neither of these arguments raise the type of "unfair prejudice" that would call for the exclusion of Dr. Dunn's opinions under Rule 403.

D. Dr. Dunn will not testify about Ethicon's state of mind.

Ethicon correctly points out that this Court has previously excluded expert testimony regarding a corporation's knowledge or state of mind.[54] Dr. Dunn does not intend to do so in these cases. However, as this Court has previously ruled: "an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her

[52] *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710-711 (S.D. W. Va. 2014).
[53] Def's Motion at 19-20.
[54] Def's Motion at 13-14.

opinions."[55] Dr. Dunn only intends to testify as to Ethicon corporate documents at trial for the purpose of explaining how the results of Ethicon's internal studies are consistent with his opinions in this case.

CONCLUSION

For the reasons stated herein, Plaintiffs respectfully request that the Court DENY Ethicon's Motion to Exclude the Testimony of Dr. Russell Dunn in its entirety.

This 9th Day of May, 2016 By: /s/ Michael H. Bowman

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[55] *Huskey v. Ethicon., Inc.*, 29 F. Supp. 3d 691, 702-703 (S.D. W. Va. 2014).

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

By: /s/ Michael H. Bowman_____